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MAIL IMPORT-ALERT 'IMPORT ALERT #57-04'

DATE: AUGUST 6, 1986

FROM: DIRECTOR, DIVISION OF FIELD INVESTIGATIONS (HFC-130)

SUBJ: IMPORT ALERT #57-04 "IMMUNO-AUGMENTATIVE THERAPY (IAT)"

TO : IMPORT PROGRAM MANAGERS

INFO: ALL MAJOR FIELD OFFICES
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BACKGROUND

"Immuno-Augmentative Therapy," (I.A.T.), is a method of cancer management proposed by Lawrence Burton, Ph.D, and available at the Immunology Researching Center, Ltd., Freeport, Grand Bahama Island, Bahamas, which opened in 1977.

In December 1974, the Immunology Research Foundation, Inc. submitted an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) seeking to initiate human investigational trials with I.A.T. agents. The IND application was placed in a FDA "inactive file" in March, 1976. Following investigation of the Freeport Clinic in 1978, the National Cancer Institute reported that records were inadequate to evaluate I.A.T.

There have been legislative efforts at both the state and federal levels, to legalize the use of I.A.T. In 1980, a federal bill failed which was intended to exempt for five years the "blood fractions" used in I.A.T. from the requirements of the Federal Food, Drug, and Cosmetic Act. Similar lobbying efforts are currently being sponsored today by the I.A.T. Patients Association. Laws were enacted in the states of Florida and Oklahoma that would have the effect of making I.A.T. agents available in those states. The Florida law was subsequently repealed.

Oklahoma requires informed consent advising that the efficacy of I.A.T. is unproven.

The American Cancer Society has stated that it has found no scientific evidence supporting the claims that I.A.T. can prevent, detect, or predict the occurrence of cancer and none was found indicating I.A.T. is safe or effective for any or all types of cancer.

Dr. Burton has also been reported to use I.A.T. in the treatment of AIDS patients.

Dr. Burton claims that I.A.T. bolsters the deficient immune mechanism present in cancer victims with specific immune human serum fractions. He claims to determine the titer of "blocking protein," "tumor antibody," "tumor complement" and "deblocking proteain" and then administers in one or a combination of the "immune substance" (except "blocking protein").

In 1984, CDC reported 16 cases of injection site abscess formation experienced by patients of the clinic. One vial of each of the human serum protein injections, four in all, were examined for sterility by CDC. All were found non-sterile. Contaminants included species of Staphylococcus, Bacillus, Acinetobacter, and Moraxella-like organisms. In 1985, Washington State laboratories tested eighteen vials of I.A.T. and reported that eight were positive for the HTLV-III antibody and all eighteen for the hepatitis B surface antigen (HBSAG). Confirmation samples tested by CDC demonstrated six of eighteen positive for HTLV-III and all eighteen positive for HBSAG. The presence of the HTLV-III antibody may indicate presence of the AIDS retrovirus. Over half of the 72 vials examined by NCI thus far have revealed these antibodies.

In July 1985, representatives of the Bahamas Ministry of Health, CDC, and the Pan-American Health Organization visited the clinic and determined that it constituted a public health hazard. The Ministry of Health ordered the clinic closed in July 1985; however, it subsequently reopened. We are not aware that any corrective actions were taken to preclude further direct hazards associated with contaminated I.A.T. agents.

GUIDANCE .

Due to the direct hazards that have been associated with I.A.T. agents, all entries, whether in personal possession or mail, should be detained. Alert your local U.S. Customs and Postal Service officials informing them of the hazards involved with these products and the importance that extra efforts be made to cover mail imports and personal possessions of persons coming from the Bahamas.

The agents have been identified as follows: 5 ml white opaque "flip top" plastic vials labeled I, II, III or, alpha 2. The name of the clinic or other identifiers are generally absent. As the agents require refrigeration, they may be smuggled in thermos bottles or similar insulated containers.

Charge: "The articles as violative within the meaning of 801(a) (3) in that they appear to lack adequate directions for use, and appear to be misbranded under section 502(f) (1) of the FD&C, and are in violation of 351(a) of the PHS Acting that they are not produced in an establishment that is licensed."

Center contact: Donald L. Legett (HFN-300), Health Fraud Staff, 8-295-8070.
ORO contact Richard R. Klug (HFC-131) Import Operations, 8-443-6553.

BURTON I. LOVE

To: IMPORT-ALERT 'IMPORT ALERT #57-04'
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